

ORIGINAL

**IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION**

BRANDON LACINAK
890 E. Columbia Ave.
Cincinnati, Ohio 45215

Case No. A 1 4 0 0 5 8 6

Judge

Plaintiff,

**COMPLAINT
& JURY DEMAND**

v.

ABUBAKAR ATIQ DURRANI, M.D.
(Served via the Hague Convention)

And

**CHILDREN'S HOSPITAL
MEDICAL CENTER**
3333 BURNET AVENUE
CINCINNATI, OH 45229

Serve: Frank C. Woodside III
1900 Chemed Center
255 E. Fifth Street
Cincinnati, OH 45202
(Serve via Certified mail)

Defendants.

REGULAR MAIL WAIVER

1611 JAN 31 P 1:50
TOMMY WALTER
CLERK OF COURTS
HAMILTON COUNTY, OH

FILED

Comes now Plaintiff, Brandon Lacinak, and files this Complaint and jury demand,
stating as follows:

KM



D105075809 INT

FACTUAL ALLEGATIONS OF PLAINTIFF

1. At all times relevant, Brandon Lacinak ("Plaintiff" or "Brandon") was a resident of and domiciled in the State of Ohio.
2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani ("Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
3. At all times relevant herein, Children's Hospital Medical Center. ("Children's Hospital") held itself out to the public, and specifically to Plaintiffs, as a hospital providing competent and qualified medical and nursing services, care, and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.
4. The amount in controversy exceeds the jurisdictional threshold of this Court.
5. The subject matter of the Complaint arises out of medical treatment by the Defendants in Hamilton County, Ohio. This Court is thus the proper venue to grant Plaintiff the relief it seeks.
6. In about late 2007, Brandon visited Children's Hospital's orthopedic department for mid to lower back pain.
7. He was referred to Dr. Durrani who administered to epidural steroid injections, which gave Brandon no relief.
8. Dr. Durrani told Brandon and his family that Brandon's back would be permanently bent if he did not undergo surgery with him.
9. Therefore, Dr. Durrani recommended Brandon undergo surgery on his thoracic and lumbar regions.
10. In late December of 2008, Dr. Durrani operated on Brandon, who was 15 years

old at the time, at Children's Hospital. Specifically, Dr. Durrani performed an anterior fusion and a posterior fusion and fixation at T5-L1.

11. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or PureGen in Brandon's surgery, without Brandon's knowledge or consent, causing Brandon harm.
12. Brandon began experiencing severe pain and new pain around his bilateral ribs.
13. At his post-op visits at Children's Hospital, Brandon visited other orthopedic doctors at who told Brandon that the cage around his ribs implanted by Dr. Durrani should not be there.
14. Further, said doctors told Brandon and his parents they were surprised that Brandon underwent such an extensive surgery.
15. After his surgery, Brandon conducted a few physical therapy sessions, which he had to discontinue because of the increased pain the sessions caused.
16. Brandon treated with Dr. Durrani and CAST until May 14, 2013.
17. Currently, Brandon experiences low to mid back pain that radiates to his bilateral lower extremities and his feet.
18. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
19. As a direct and proximate result of this surgery and Dr. Durrani's actions, Brandon has suffered, *inter alia*, physical, emotional, and monetary damages.
20. Neither Brandon nor his parents knew that Dr. Durrani used Infuse/BMP-2 in his surgery until he contacted her undersigned counsel.

INFUSE/BMP-2

21. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.
22. BMP-2 is manufactured, marketed, sold and distributed by Medtronic under the trade name "Infuse."
23. Dr. Durrani is a consultant for Medtronic.
24. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.
25. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.
26. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.
27. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.
28. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE").
29. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by

the FDA, and thus such procedures and/or use of non-FDA approved componetry is termed “off-label.”

30. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as “ectopic” or “exuberant”) bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

31. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

32. Dr. Durrani and Children’s Hospital personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

33. Dr. Durrani used BMP-2 in Plaintiff in manners not approved by Medtronic or the FDA.

34. Plaintiff was not informed by Dr. Durrani that Dr. Durrani used Infuse/BMP-2 in his surgery.

35. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in his surgery(ies) in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2’s manufacturer.

36. Plaintiff would not have consented to the use of BMP-2 in his body if informed of the risks by Dr. Durrani, or any Children’s Hospital personnel.

37. The written informed consent of Dr. Durrani signed by Plaintiff lacked the disclosure of Infuse/BMP-2’s use in his procedure(s).

38. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, Children's Hospital personnel.
39. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.
40. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.
41. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.
42. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.
43. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN

44. Dr. Durrani oftentimes used Puregen when performing surgeries.
45. Puregen is a product produced by Alphatec Spine.
46. Dr. Durrani was and is a paid consultant for Alphatec Spine.
47. Dr. Durrani has an ownership stake in the Alphatec Spine.
48. Puregen has never been approved by the FDA for any human use.
49. Puregen is now removed from the market for any use.
50. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.
51. Dr. Durrani, CAST staff and employees and Children's Hospital personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.
52. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

53. Plaintiff was not informed by Dr. Durrani, CAST staff and employees or any Children's Hospital personnel that Dr. Durrani used Puregen in their surgery.

54. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in his surgery(ies) in a manner that was not approved by the FDA.

55. Plaintiff would not have consented to the use of Puregen in his body if informed of the risks by Dr. Durrani, CAST staff and employees, or any Children's Hospital personnel.

56. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Puregen's use in their procedure(s).

57. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any Children's Hospital personnel.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

58. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

59. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

60. As a direct and proximate result of the aforementioned negligence and deviation

from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment.

COUNT II: BATTERY

61. Dr. Durrani committed battery against Plaintiff by performing a surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, *inter alia*, by using BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.
62. Plaintiff would not have agreed to the surgeries if they knew the surgery(ies) was/were unnecessary, not approved by the FDA, and not indicated.
63. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, loss of the ability to perform usual and customary activities, and incurred substantial medical expenses and treatment.

COUNT III: LACK OF INFORMED CONSENT

64. The informed consent forms from Dr. Durrani which they required Plaintiff to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani required an informed consent release.

65. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiff's surgery(ies).
66. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with his surgery(ies) and procedures.
67. Plaintiff subsequently developed severe and grievous injuries as a direct and proximate result of lack of informed consent.
68. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.

COUNT IV: INTENTIONAL INFILCTION OF EMOTIONAL DISTRESS

69. Dr. Durrani's conduct as described above was intentional and reckless.
70. It is outrageous and offends against the generally accepted standards of morality.
71. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.
72. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

73. Dr. Durrani made material, false representations to Plaintiff and his insurance company related to Plaintiff's treatment including: stating the surgeries were necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the

insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.

74. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiff's surgery when he had a duty to disclose to Plaintiff his planned use of the same.

75. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo his surgery(ies).

76. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

77. Dr. Durrani made the misrepresentations both before, during and after the surgery(ies) with the intent of misleading Plaintiff and his insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgery(ies), and to induce Plaintiff to undergo the surgery(ies) without regard to medical necessity and only for the purpose of receiving payment.

78. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's and/or at Children's Hospital.

79. Plaintiff justifiably relied on the misrepresentations because a patient has a right to trust his doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

80. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery(ies) which were paid for in whole or in part by his insurance company, and

suffered severe and grievous injuries, paralysis, new and different pain, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, loss of ability to perform usual and customary activities, and incurred substantial medical expenses and treatment.

COUNT VI: SPOLIATION OF EVIDENCE

81. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled (“spoiled”) Plaintiff’s records, billing records, paperwork and related evidence.
82. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.
83. Dr. Durrani’s conduct was designed to disrupt Plaintiff’s potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

CHILDREN’S HOSPITAL COUNTS:

COUNT I: VICARIOUS LIABILITY

67. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of Children’s Hospital through September, 2008.
68. Defendant Dr. Durrani was performing within the scope of his employment with Children’s Hospital during the care and treatment of Plaintiff.
69. Defendant Children’s Hospital is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.
70. Defendant Children’s Hospital is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

71. As a direct and proximate result of Defendant Children's Hospital's acts and omissions, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment.

**COUNT II: NEGLIGENT HIRING, SUPERVISION, CREDENTIALING &
RETENTION**

72. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiff constitute physician negligence and medical malpractice.

73. Children's Hospital negligently credentialed, hired and retained Dr. Durrani as a credentialed physician by:

- a. Allowing Dr. Durrani to repeatedly violate the Children's Hospital bylaws with it's full knowledge of the same;
- b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for privileges and employment at Children's Hospital;
- c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by Children's Hospital staff, Dr. Durrani's patients and by others;
- d. Failing to properly supervise Dr. Durrani's treatment of patients.

74. The Safe Medical Device Act required entities such as Children's Hospital to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

75. Such disregard for and violations of federal law represents strong evidence that

Children's Hospital negligently granted and retained privileges for Dr. Durrani.

76. Children's Hospital further breached its duty to Plaintiff, inter alia, by not controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at Children's Hospital.

77. As a direct and proximate result of the negligent credentialing and retention of Dr. Durrani, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment that Plaintiff would not otherwise have incurred had Dr. Durrani not been credentialed by Children's Hospital.

COUNT III: SPOLIATION OF EVIDENCE

78. Children's Hospital through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, paperwork and related evidence.

79. Children's Hospital through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

80. Children's Hospital's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT IV: FRAUD

84. Children's Hospital sent out billing to Plaintiff at their home following their surgery(ies) at Children's Hospital.

85. The exact dates these medical bills were sent out are reflected in those medical bills.

86. These bills constituted affirmative representations by Children's Hospital that the charges related to Plaintiff's surgery were medically appropriate and properly documented.
87. The bills were sent with the knowledge of Children's Hospital that in fact Plaintiff's surgery was not appropriately billed and documented and that the service rendered at Children's Hospital associated with Dr. Durrani was not appropriate.
88. The bills sent by Children's Hospital to Plaintiff falsely represented that Plaintiff's surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.
89. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for Children's Hospital's services in association with Dr. Durrani's surgery.
90. As a direct and proximate result of this reliance on the billing of Children's Hospital, Plaintiff incurred medical bills that they otherwise would not have incurred.
91. Children's Hospital also either concealed from Plaintiff that Infuse/BMP-2 or Puregen would be used in Plaintiff's surgery, or misrepresented to Plaintiff the nature and necessity of the surgery and the particular risks involved therein.
92. Children's Hospital's concealments and misrepresentations regarding Infuse/BMP-2 or Puregen and the nature, necessity, and risks of Plaintiff's surgery were material facts.

93. Because of its superior position and professional role as a medical service provider, Children's Hospital had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

94. Children's Hospital intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at Children's Hospital.

95. Plaintiff was unaware that Infuse/BMP-2 or Puregen would be used in Plaintiff's surgery and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiff's spine.

96. Had Plaintiff known before Plaintiff's surgery/ies that Infuse/BMP-2 or Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surger/ies with Dr. Durrani at Children's Hospital.

97. As a direct and proximate result of Children's Hospital's concealments and/or misrepresentations regarding Infuse/BMP-2 or Puregen, and the nature and necessity of the surgery performed by Dr. Durrani at Children's Hospital, Plaintiff sustained, *inter alia*, economic, and non-economic (including physical, emotional) damages.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs request and seek justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;

3. Lost income and benefits;
4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that his injuries are catastrophic under Ohio Rev. Code §2315.18;
9. All incidental costs and expenses incurred as a result of his injuries;
10. The damages to his credit as a result of his injuries;
11. Punitive damages;
12. Costs;
13. Attorneys' fees;
14. Interest;
15. All property loss;
16. All other relief to which they are entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiffs seek in excess of \$25,000.

Respectfully Submitted,


Debra Nelson (# 0077538) (89945)
Attorney for Plaintiff
637 W. 7th Street
Cincinnati, OH 45203
513-729-1999 Fax: 513-381-4084
dnelson@ericdeters.com

JURY DEMAND

Plaintiff makes a demand for a jury under all claims.

Debra Nelson / Stephanie Collins
Debra Nelson (89945)

FILED



2014 JAN 31 P 1:50

COMMON PLEAS COURT

HAMILTON COUNTY, OHIO

CLERK OF COURTS

HAMILTON COUNTY, OH

Brandon Lacinak

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CASE NO.

VS

WRITTEN REQUEST FOR SERVICE

TYPE OF PAPERS TO BE SERVED ARE

Abubakar Atig Duranimo

Complaint with Jury Demand

Notice to File For Extension of Time To File Aon

PLEASE CHECK IF THIS IS A

DOMESTIC CASE

PLAINTIFF/DEFENDANT REQUESTS:

EXPRESS MAIL SERVICE _____

CERTIFIED MAIL SERVICE

REGULAR MAIL SERVICE _____

PERSONAL SERVICE _____

RESIDENCE SERVICE _____

PROCESS SERVICE _____

FOREIGN SHERIFF _____

ON Children's Hospital Medical Center
Serve: Frank C. Woodside III

1900 Children Center

255 E. 5th Street

Cincinnati, OH 45202

Debra Nelson
ATTORNEY

859-363-1900

PHONE NUMBER

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DO77538

ATTORNEY NUMBER

COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO FILED

REQUEST AND INSTRUCTIONS FOR ORDINARY MAIL SERVICE
2014 JAN 31 PM 1:50

Brandon Lacinak

Plaintiff

-vs-

CLERK OF COURTS
INSTRUCTIONS TO THE CLERK

A 1 4 0 0 5 8 6

CASE NUMBER:

Abubakar Atig Durrani, MD, et al

Defendant

IF SERVICE OF PROCESS BY CERTIFIED MAIL IS RETURNED BY THE POSTAL AUTHORITIES WITH AN ENDORSEMENT OF "REFUSED" OR "UNCLAIMED" AND IF THE CERTIFICATE OF MAILING CAN BE DEEMED COMPLETE NOT LESS THAN FIVE (5) DAYS BEFORE ANY SCHEDULED HEARING, THE UNDERSIGNED WAIVES NOTICE OF THE FAILURE OF SERVICE BY THE CLERK AND REQUESTS ORDINARY MAIL SERVICE IN ACCORDANCE WITH CIVIL RULE 4.6 (C) OR (D) AND CIVIL RULE 4.6 (E).

Debra Nelson
ATTORNEY OF RECORD (TYPE OR PRINT)

1/31/14
DATE

Debra Nelson / Stephanie Collins
ATTORNEY'S SIGNATURE (89945)